

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

WARNING LETTER

2000-DT-05

December 17, 1999

Mr. Tim Patton
Chief Executive Officer
Health Care Solutions, Inc.
3796 Plaza Drive, Suite 2
Ann Arbor, MI 48108

Dear Mr. Patton:

An inspection of your medical oxygen manufacturing operation, located at 595 Bradford, Pontiac, MI 48341, was conducted on November 3 & 5, 1999 by Investigator Catherine V. Quinlan. At the conclusion of the inspection a FORM FDA-483, list of Inspectional Observations (copy attached), was issued to Mr. Samuel F. Thompson, General Manager. The medical oxygen sold by your firm is adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

The medical oxygen is adulterated based on inspectional evidence which revealed serious deviations from Current Good Manufacturing Practice for Finished Pharmaceuticals, Part 211 (21CFR211), as follows:

1. You did not have a designated Quality Assurance Unit, nor any written quality assurance procedures for the medical gas operations.
2. Batch records since July 1999 had not been signed as reviewed by a responsible management individual, prior to release and distribution of the product.
3. A shipment of bulk liquid oxygen(LOX) received on Saturday, October 23, 1999 from [REDACTED] was not tested for identity and potency, prior to being used to fill patient customers home liquid storage units and to fill cylinders of compressed oxygen gas at your Pontiac facility.

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4. There was no documentation that any training has been given to the employees currently performing filling of compressed oxygen or any GMP training in the filling of liquid or compressed medical oxygen.
 5. A unique lot or batch number was not assigned to each separate fill of the vehicle mounted LOX vessels used for home delivery of medical oxygen.
 6. The written Standard Operating Procedures on file at Pontiac, MI were reportedly prepared for your Akron, OH facility. They do not reflect the current procedures at Pontiac, MI. For example, the SOP's for master labels and label receipt and inventory controls; lot or batch numbering systems; and the LG TRANSFILL OF LOX procedures all differed from the practices found in use in the Pontiac facility. Furthermore these SOP's were not signed and dated by a management individual responsible for the Pontiac facility.
 7. There was no documentation of a prefill inspection of the large cryogenic vessels (LP180) used to supply LOX for filling compressed cylinders.
 8. Calibration of equipment, such as thermometers and pressure and vacuum gauges, had not been performed as called for in your SOP Procedure M; there was no documentation of daily calibration of the vacuum gauge; and there was no SOP for calibration of the [REDACTED] Oxygen Analyzer.
 9. Upon receipt of a new batch of bulk LOX into your oxygen stand tank, the practice has been to calibrate the [REDACTED] Analyzer prior to moving it to the stand tank to perform the necessary assay test. This is contrary to the manufacturer's instruction manual, which states the instrument should not be moved after calibration.

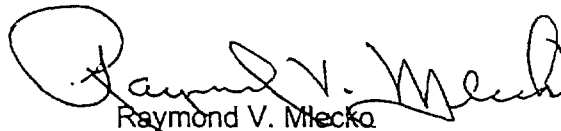
The above is not intended to be an all-inclusive list of deviations which may exist at your firm. It is your responsibility to ensure that your firm is in full compliance with the Act and regulations promulgated thereunder. Other Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

We request that you take prompt action to correct these deviations. Failure to make prompt corrections may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing, within fifteen (15) working days of your receipt of this letter, of the specific steps you have taken to correct the noted deviations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, please state the reason for the delay, and the time in which the corrections will be completed.

Your response should be directed to this office to the attention of Mr. Melvin O. Robinson, Compliance Officer., (313) 226-6260, Extension 128

Sincerely yours,



Raymond V. Mlecko
District Director
Detroit District

Enclosure

Cc: Mr. Samuel F. Thompson
General Manager
Health Care Solutions, Inc.
595 Bradford
Pontiac, MI 48341